REMARKS

This amendment, submitted in response to the Office Action dated May 29, 2003, is believed to be fully responsive to each point of objection raised therein. Accordingly, favorable reconsideration is respectfully requested.

Claims 6, 7, and 14-21 are pending in the application. The Examiner rejected claims 14-20 under 35 U.S.C. § 102(e) as being anticipated by Stern et al., (USP 5,631,734). The Examiner rejected claims 6 and 21 under 35 U.S.C. § 103(a) as being unpatentable over Gleisner (USP 5,547,702) in view of Tisone (WO 98/04358). Claim 7 has been rejected under 35 U.S.C. §103(a) as being unpatentble over Gleisner in view of Tisone as applied to claims 6 and 21 above, and further in view of Heyneker (USP 6,057,100). Applicant submits the following in traversal of the rejections.

Rejection of claims 14-20 as being anticipated by Stern

Claims 14 and 17 describe systems for reading a test piece comprising a strip-like substrate bearing thereon numbers of known specific *binding agents* which are different from each other and are *arranged in a line* at *predetermined intervals* in the longitudinal direction of the strip-like substrate.

Assuming arguendo, the presynthesized probes of Stern, as cited by the Examiner, are binding agents as described in the present invention, there is no evidence that the probes are arranged in a line at predetermined intervals in the longitudinal direction of the strip-like substrate. Stern merely indicates that the substrate 230 comprises a number of presynthesized probes on its surface (column 3, lines 43-45), but it is unclear as to whether the probes are arranged in a line at predetermined intervals.

In particular, when the substrate of Stern is read, (see flowchart of Fig. 2), it must be determined whether the scan line is complete. If the scan line is complete, it will move on an XYZ stage to a next scan line, otherwise, it will continue to scan. This is an indication that the probes are not arranged in *predetermined* intervals since the system must be prompted to verify whether there are more probes to be scanned.

The Examiner maintains that the data of Stern are acquired continuously along a line (Office Action p. 4), therefore, it appears the Examiner is reasoning that the binding agents are arranged on a continuous line. Merely because information is *acquired* in a continuous line does not mean that the binding agents are *arranged* in a line at predetermined intervals. The entire substrate could be covered with various arrangements of probes, while data can be acquired in a continuous line.

The Examiner additionally maintains that the XYZ translation table of Stern is a conveyor which conveys the strip-like substrate or the exciting light source to impart relative movement between the strip-like substrate and the exciting light source, said relative movement being along a single axis. In Stern, the XYZ translation table clearly moves in three different directions and not along a single axis. In addition, Stern requires that three axes of movement be employed in order to scan a substrate, whereas the present invention only requires a single axis of movement to scan a substrate. (Claims 14 and 20). The claims describe a species not taught by the more general multi-axes control.

Therefore, the system of the present invention is more efficient and less complicated then Stern. In addition, the system of Stern require more expensive control mechanisms and there is

an increased risk that the accuracy in scanning and light detection is reduced. Furthermore, due to the multiple directions necessary for scanning, scanning speed is decreased.

If Stern moved in a single axis, then only a part of the substrate would be scanned, leading to an incomplete scanning of the substrate of Stern. This would render Stern inoperable for it intended purpose, and thus cannot support the rejection.

The Examiner additionally states that the *Applicant* does not provide any evidence to show why the scanning system taught by Stern cannot be used to scan the strip-like test piece in the longitudinal direction. Applicant submits that the *Examiner* and not the *Applicant* has the burden of establishing a prior art rejection. The Applicant is merely indicating that the Examiner is making assumptions in order to support a rejection of the claims which are not prima facie disclosed in the prior art. The Examiner bears the burden of supporting any prima facie conclusion of unpatentability. Arguments based on assumptions, does not meet that burden. If the Examiner does not produce a prima facie case, the Applicant is under no obligation to submit evidence. MPEP 2142.

With respect to the Examiner's statement regarding *In re Kotzab*, the Examiner stated that the decision in *In re Kotzab* is not related to the rejection since the Examiner did not cite this case law in the previous rejection. This is irrelevant. Federal Circuit precedent is applicable.

The Examiner additionally states *In re Kotzab* is nonanalagous to the present situation. The Examiner maintains *In re Kotzab* states, "Evans does not teach or suggest the use of a single temperature sensor to control a plurality of flow control valves" while Stern discloses scanning system which can scan a test piece along multiple axes. It appears the Examiner is misinterpreting *In re Kotzab*.

In *In re Kotzab*, the claims were drawn to an injection molding method using a *single* temperature sensor to control a plurality of flow control valves. The primary reference disclosed a *multizone device having multiple sensors*, each of which controlled an associated flow control valve, and also taught that one system may be used to control a number of valves. The court found that there was insufficient evidence to show that one system was the same as one sensor. *While the control of multiple valves by a single sensor rather than by multiple sensors was a "technologically simple concept," there was no finding "as to the specific understanding or principle within the knowledge of the skilled artisan" that would have provided the motivation to use a single sensor as the system to control more than one valve.* 217 F.3d at 1371, 55 USPQ2d at 1318. MPEP 2143.01.

The present invention describes a conveyor moving along a *single* axis. The conveyer of Stern, moves along multiple axes. There is no indication in Stern that one of ordinary skill in the art would be motivated to convey a substrate in a single axis. In particular, conveying the substrate of Stern along a single axis would lead to an incomplete scanning of the substrate as indicated above. Therefore, *In re Kotzab* is analagous to the present situation and its holding should apply.

The claims further describe an analysis means which relates the result of detection of the fluorescence with the positioning in which the fluorescence is emitted and thereby determines the specific binding agent on the test piece with which the substance derives from the sample organism is hybridized and determines a difference between substances derived from sample organisms on the basis of specific binding agents.

The Examiner refers to a Southern blot assay for teaching hybridization signals can be scanned as described in claims 17 and 18. The relevancy of the Examiner's argument with respect to a Southern blot assay is unclear since is does not appear that a Southern blot assay is mentioned anywhere in Stern. Also, it is unclear what the scanning of hybridization *signals* has to do with determining the difference between the substances derived from sample organisms on the basis of the binding agents with which the substances derived from the respective sample organisms are hybridized with each other, as described in claim 17. In addition, claim 18 describes the specific binding agents are cDNA's and not the analysis of fluorescence, as argued by the Examiner.

The Examiner's reliance on detection of two fluorescence signals misses the mark. Any detection of different labeling substances does not relate to differences on the binding agents, those bound to the substrate. While the detection of different fluorescent material may be used by an operator for analysis, nothing in Stern requires the analysis to be performed by the system. The analysis performed by an operator does not comprise an analysis unit structural feature.

Again, the Examiner raises the argument that the *Applicant* has not provided evidence to show why the system taught in Stern cannot perform the functions of the analysis means as recited in claims 17 and 18. As stated earlier, the burden is on the Examiner, not the Applicant, to establish a prima facie case. Therefore, the Examiner has not shown that the system *can* perform the functions of analysis described in claim 17. Particularly because there is no indication in the reference, and the Examiner is merely hypothesizing, as a result of impermissible hindsight, as to what the system of Stern can do, in order to support a rejection.

In addition, the Examiner has not established that the binding agents are cDNA as described in claims 15 and 18. For at least this reason, any subsequent Office Action should be made on a non-final basis.

For the above reasons, claims 14 and 17 and their dependent claims should be deemed patentable.

Rejection of claims 6 and 21 as being unpatentable over Gleisner in view of Tisone

The Examiner maintains that a combination of Gleisner and Tisone teach the elements of claims 6 and 21.

The Examiner maintains that since Gleisner teaches cutting a web into predetermined shorter lengths containing a preset number of test strips that Gleisner teaches a cutting means as described in claim 6. The Examiner cites Gleiser claims 1 and 5 and the last paragraph of column 1 in support. However, the respective claims and paragraph cited by the Examiner merely describe a method of cutting a web. For example, cutting the web into shorter lengths of web containing a plurality of test strips for further processing. However, Gleisner has provided no indication as to how the web is cut or in what direction. Therefore, the respective claims and paragraph cited by the Examiner do not describe a cutting *means* or apparatus that will be used to cut a substrate in a *first direction.*

In addition, claim 6 further describes known specific binding agents which are different from each other and are arranged in a line at predetermined intervals in the longitudinal direction of the strip-like substrate. In Gleisner, there appears to be only one, if any, binding agent on the strips. The strips of Gleisner contain one reagent at a distal end of the strip. The *reagent* on the strip is based upon what analyte is being tested. Column 2, lines 65-66. There is no indication

that more than one analyte is being tested with a given strip, therefore, there would be no reason to have more than one reagent on the substrate. Therefore, Gleisner does not disclose binding agents which are different from each other and are arranged in a line at predetermined intervals in the longitudinal direction of the strip like substrate.

The Examiner additionally maintains Gleisner discloses a conveyor as described in claim 6. The Examiner maintains Gleisner teaches the substrate 10 having a strip 11 of permeable material is continuously fed by a suitable conveyor, therefore Gleisner discloses a conveyor which conveys the sheet-like substrate relative to each other in a second direction which is substantially perpendicular to the first direction.

However, Applicant submits that this aspect of the claim additionally includes the plurality of applicators and that the claim more accurately describes a conveyor which conveys the plurality of applicators or the sheet like substrate relative to each other in a second direction. Therefore, the Examiner has failed to establish the interrelationship between the plurality of applicators and the sheet-like substrate, as described in claim 6.

The Examiner concedes Gleisner does not teach a plurality of applicators and applying the plurality of known specific binding agents in lines which extend in the second direction and are arranged at predetermined intervals as described in claim 6, and cites Tisone to cure the deficiencies.

Applicant submits that Tisone does not disclose the applicators as described in claim 6. Tisone teaches multiple dispensers mounted to handle one or more reagents (page 15, lines 25-26), however, the positioning of the applicators are not disclosed. In particular, Tisone does not

disclose that the applicators are arranged at predetermined intervals in a first direction relative to the sheet-like substrate, as described in claim 6.

It addition, it would appear that in Tisone, the applicator and the conveyor are moving in the same direction. The conveyor is conveying the sheet-like substrate in the same direction of which the applicators are arranged. See. Fig. 9. Therefore, the conveyor is not conveying the sheet-like substrate in a second direction which is substantially perpendicular to the first direction of which the applicators are arranged.

For the above reasons, claim 6 and dependent claims 7 and 21 should be deemed patentable.

Rejection of claim 7 as being unpatentble over Gleisner in view of Tisone and further in view of Heyneker

The Examiner concedes Gleisner and Tisone do not teach cDNA's as specific binding agents and cites Heyneker to cure the deficiency. Heyneker teaches oligonucleotide arrays which are equal to 2 to 500 mer and does not teach cDNA's, which are equal to or more than 500 mer.

Assuming arguendo Heyneker teaches cDNA, the reference does not make up for the deficiencies of Gleisner and Heyneker.

Further, Applicant notes that Gleisner and Tisone teach test strips containing a reagent. A biological fluid is placed on the reagent in order to detect analytes which could be used to diagnose, for example, glucose. Gleisner (Column 1, lines 12-23) and Tisone (page 1, lines 18-21). Heyneker pertains to the generation of oligonucleotide arrays for purposes of hybridization. Column 1, lines 10-20. It is clear to one of ordinary skill in the art that the detection of analytes in biological fluids is clearly a different field that the hybridization of oligonucleotide arrays.

The reaction with an indicator dye (Gleisner) differs fundamentally from hybridization analysis (Heyneker).

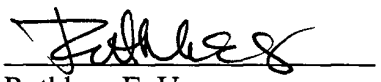
The Examiner also cited MPEP 2144.07 and 2144.09 in support of the motivation for the substitution. MPEP 2144.07 and 2144.09 which pertain to chemical compounds and their structures, is nonanalagous to the present situation which pertains to an *apparatus* for manufacturing a test piece. Therefore, claim 7 should be deemed patentable.

Applicant has added claims 22-25 to provide a more varied scope for the present invention.

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,



SUGHRUE MION, PLLC
Telephone: (202) 293-7060
Facsimile: (202) 293-7860

WASHINGTON OFFICE
23373
CUSTOMER NUMBER

Ruthleen E. Uy
Registration No. 51,361

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